

TABLE 1
Demographic Characteristics

	Total Cases n=180
Age (years)	
Mean	40.2
Standard Deviation	±10.7
Range	12-82
Gender	
Female	161 (89.4%)
Male	19 (10.6%)
Side	
Unilateral	
Right	46 (25.6%)
Left	46 (25.6%)
Bilateral	88 (48.9%)

TABLE 2
Diagnosis

	Total Cases Right Side		Total Cases Left Side	
	n=134		n=134	
	n	%	n	%
1. Osteoarthritis	73	54%	76	57%
2. Rheumatoid Arthritis	7	5%	5	4%
3. Traumatic Arthritis	45	34%	40	30%
4. Malignancy	0	0%	0	0%
5. Benign Neoplasm	1	1%	1	1%
6. Functional Deformity	9	7%	10	7%
7. Revision: partial implant	11	8%	12	9%
8. Revision: total implant	43	32%	44	33%
9. Avascular Necrosis	39	29%	38	28%
10. Ankylosis	61	46%	65	49%
11. Fracture	14	10%	8	6%

TABLE 3
Study Visits Schedule

	Vs 1: Screen Base-line	Vs 2: Surgery	Vs 3: 1 month follow- up	Vs 4: 3 month follow- up	Vs 5: 6 month follow- up	Vs 6: 1 year follow- up	Vs 7: 1.5 years follow-up	Vs 8: 3 years follow- up	Vs 9: 4 years follow- up	Vs 10: 5 years follow- up	Vs 11: 6 years follow- up
Inclusion/ Exclusion criteria met	X										
Informed Consent	X	Or X									
Preoperative Record: Medical history clinical examination	X										
Radiographic Assessment	X	*	X	X	X	X	X	X	X	X	X
Jaw pain & function: Jaw pain intensity, Interference with eating, Maximal incisal opening, Occlusion, Anterior open bite, cross bite	X		X	X	X	X	X	X	X	X	X
Operative Record		X									
Patient satisfaction with surgery			X	X	X	X	X	X	X	X	X
Wound healing			X	X	X	X	X	X	X	X	X

* immediate postoperative x-ray used for comparison only.

TABLE 4
Patient Accountability

	Follow-Up Time Periods								
	1mo	3mos	6mos	1yr	1.5yr	3yrs	4yrs	5yrs	6yrs
Theoretically Due (all cases)	180	171	160	138	109	57	23	10	9
Deaths	1	1	1	1	1	2	0	1	1
Permanent Removal of Total Joint	0	0	1	2	2	0	0	0	0
Have Follow-Up (all cases)	170	153	143	116	89	45	22	4	5
Percent Follow-Up	95.0	90.1	90.6	86.2	84.4	82.5	95.7	50.0	66.7
Have Follow-Up (all joints)									
right side only	41	38	37	31	27	10	7	2	1
left side only	43	36	38	30	21	13	7	0	0
bilateral	86	79	68	55	41	17	8	2	4
Total # of joints	256	232	211	171	130	57	30	6	9

TABLE 5
Secondary Efficacy Endpoints
Visits 1 - 11

		Jaw Pain	Interference with Eating	MIO
Visit (interval)	N	Mean ± SD	Mean ± SD	Mean ± SD
Vs 1 (baseline)	180	8.1 ± 2.6	8.0 ± 2.3	19.2 ± 9.5
Vs 3 (1mo)	170	4.3 ± 2.4	4.5 ± 2.3	25.0 ± 6.2
Vs 4 (3 mos)	153	3.6 ± 2.5	3.4 ± 2.5	29.2 ± 6.0
Vs 5 (6 mos)	143	3.1 ± 2.3	3.0 ± 2.5	30.1 ± 6.4
Vs 6 (1 year)	116	2.9 ± 2.4	2.8 ± 2.4	30.7 ± 6.0
Vs 7 (1.5 yr)	89	3.4 ± 2.4	3.0 ± 2.4	30.7 ± 5.9
Vs 8 (3 yrs)	45	2.6 ± 2.3	2.5 ± 2.1	29.8 ± 6.1
Vs 9 (4 yrs)	22	3.2 ± 2.4	3.5 ± 3.1	30.3 ± 6.1
Vs 10 (5 yrs)	4	2.6 ± 1.7	3.2 ± 2.5	28.5 ± 3.8
Vs 11 (6 yrs)	5	2.9 ± 2.3	3.0 ± 2.3	26.6 ± 3.4

Note: Visit 2 is the day of surgery.

[illegible]

